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2 UNITED STATES DISTRICT COURT  
3 DISTRICT OF MASSACHUSETTS

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5 IN RE: NEW ENGLAND COMPOUNDING ) MDL NO. 13-02419-RWZ  
6 PHARMACY CASES LITIGATION )  
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14 BEFORE: THE HONORABLE JENNIFER C. BOAL  
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18  
19 **STATUS CONFERENCE**  
20 **AND**  
21 **MOTIONS HEARING**  
22

23 John Joseph Moakley United States Courthouse  
24 Courtroom No. 12  
25 One Courthouse Way  
Boston, MA 02210

May 19, 2016  
11:30 a.m.

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## P R O C E E D I N G S

(The following proceedings were held in open court before the Honorable Jennifer C. Boal, Magistrate Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, One Courthouse Way, Boston, Massachusetts, on May 19, 2016.)

COURTROOM DEPUTY CLERK YORK: Court is in session. The Honorable Jennifer C. Boal presiding. You may be seated.

Today is May 19th, 2016. We're on the record in the matter of NECC. The case number is 13-MD-2419. Will counsel please identify themselves for the record, starting with the Plaintiffs' Steering Committee.

MR. CHALOS: Mark Chalos on behalf of the PSC.

THE COURT: There's no one on the phone. So --

MS. GREER: Actually --

THE COURT: There is?

MS. GREER: Excuse me. Someone is on hold. They just sent me an email.

COURTROOM DEPUTY CLERK YORK: No one called for a number.

MS. GREER: They didn't?

COURTROOM DEPUTY CLERK YORK: No.

(Pause.)

THE COURT: Anyway, you might as well go forward with the introductions. I was hoping we didn't have to care so

1 much about the microphones.

2 MR. GASTEL: Ben Gastel on behalf of the Plaintiffs'  
3 Steering Committee.

4 MS. MARTIN: Annika Martin on behalf of the  
5 Plaintiffs' Steering Committee.

6 MR. TARDIO: Chris Tardio for the Tennessee Clinic  
7 Defendants.

8 MR. GIDEON: C.J. Gideon for the same defendants.

9 MR. WOLK: Christopher Wolk on behalf of the Premier  
10 defendants.

11 MR. BLUMBERG: And Jay Blumberg on behalf of the  
12 Premier defendants.

13 JUDGE BOAL: Good morning, everyone.

14 MR. GIDEON: Good morning.

15 (Pause.)

16 THE COURT: Why don't we get started and, hopefully,  
17 we can have them join in progress.

18 So, the first issue -- I know there was an agenda,  
19 but I did -- I think I alerted everyone to this in the  
20 electronic order. I was interested in the status of the  
21 motion related to Michael O'Neal and whether or not there's  
22 been a resolution or we anticipate going forward with that.

23 MR. GASTEL: Your Honor, the parties have been  
24 working on a stipulation that would moot that motion. We  
25 haven't quite completed that. We've kind of exchanged some

1 drafts. There's a couple of small sticking points, but it  
2 seems like we will work through that and, hopefully, we -- I  
3 anticipate being able to get that done before the next status  
4 conference.

5 MR. TARDIO: I agree. I think we've reached  
6 basically an agreement and it's just memorializing it.

7 THE COURT: So, would it be possible if I set a date  
8 of two weeks to get it done? I just want to be sure there's  
9 not a lingering issue with discovery.

10 MR. TARDIO: I think that's fair.

11 MR. GASTEL: We would agree to that, your Honor.

12 THE COURT: All right. So, we will enter a deadline  
13 of two weeks to wrap that up.

14 So, the first motion on the agenda is the motion to  
15 strike Matthew Lee as a case-specific expert. I have read the  
16 pleadings in that case. So, I will hear briefly from the  
17 parties and then I had a couple of questions.

18 MR. TARDIO: Thank you, your Honor.

19 Since I know that the Court, based on that comment --  
20 and my assumption coming in was that you had read the briefs.  
21 So, I won't just recite the briefs. I do want to address a  
22 few points raised in the plaintiffs' response.

23 First and foremost, I don't, frankly, understand the  
24 argument that Dr. Lee is a case-specific causation expert. I  
25 don't think any fair and reasonable reading of his reports

1 would in any way -- I don't think you can even stretch to make  
2 the argument that he's a case-specific causation expert.

3           The essence of his opinion, the reason he is going to  
4 be called, based on the report, is to come to trial and say  
5 that STOPNC fell below the standard of care in purchasing  
6 compounded medications from New England Compounding Center,  
7 and under the definitions set forth by the Court and agreed to  
8 by the parties, he is a common expert and, again, he's not a  
9 medical causation expert. I don't understand -- I don't  
10 understand that argument. I don't think it has any merit.

11           The second point I wanted to address from the  
12 plaintiffs' response is what I gather to be an argument that  
13 this is just how MDLs work, and here is two -- here are two  
14 examples in the two orders that are cited in the plaintiffs'  
15 response brief, the Acutane litigation and the Fen-Phen  
16 litigation.

17           The Acutane order that is cited in the plaintiffs'  
18 response says basically that you can disclose doctor whatever,  
19 Dr. Smith, in the common phase, and then you can disclose Dr.  
20 Smith again in the case-specific phase with case-specific  
21 opinions. I don't disagree with that, and that is fine.  
22 That's not what's happening here. So, the Acutane order  
23 doesn't really have any application to the situation here and,  
24 frankly, it's not the order that was entered that we're  
25 following in this case.

1           Secondly, the Fen-Phen order says specifically that  
2   you could do this, that you could disclose a generic or common  
3   expert and then individual plaintiffs could disclose a  
4   different or additional common or generic expert. If the  
5   Fen-Phen order was the order in this case, we wouldn't have an  
6   argument. We wouldn't have filed a motion, but it's not. The  
7   Court entered a phased approach. The Court didn't follow what  
8   was done in Fen-Phen. Therefore, the Fen-Phen order -- while  
9   that may be the way that the plaintiffs want this to work,  
10   that's not the order that's in place in this case.

11           Lastly, there is prejudice. There is prejudice  
12   because the easiest thing to point to is the cost. You're  
13   talking two or three days of work, travel and prep and then  
14   taking the expert, plus the expert fee. On top of that, you  
15   do have real prejudice to our case because you're adding an  
16   expert, presumably, who the plaintiff thinks -- plaintiffs  
17   think is an effective expert or they wouldn't have disclosed  
18   him. So, there is prejudice and I'm happy to address any  
19   specific questions the Court has.

20           THE COURT: So, I have read the expert reports in the  
21   three cases, and it seems to me that most of it is the  
22   wrongdoing of NECC and other entities, but there was, I think,  
23   one or two paragraphs specific to each plaintiff. Are you  
24   objecting to the expert giving testimony just pertaining to  
25   those one or two paragraphs?

1 MR. TARDIO: It depends on what that testimony is.  
2 If he comes in and says STOPNC fell below the standard of  
3 care, the compounded drugs were dangerous, they shouldn't have  
4 bought them, and it injured this plaintiff, I think that is  
5 100 percent a common-expert opinion.

6 If this expert is going to come in and say Ms. Wray  
7 suffered a fungal infection that was due to the introduction  
8 of the Exserohilum fungus in her spinal column and explain  
9 that pathology, that is fair, but that's not what this expert  
10 is, I don't believe, declared to testify to.

11 So, if it were a true causation opinion, we would  
12 have absolutely no objection to him giving a specific medical  
13 causation opinion. It's not fair for him to come in and give  
14 a litany of criticisms and then just stick the plaintiff's  
15 name at the end and say, well, it only caused injury to this  
16 specific plaintiff.

17 THE COURT: And I take it from your comments, that  
18 Mr. Lee has not been deposed; is that right?

19 MR. TARDIO: Correct.

20 THE COURT: And I also take it that there -- because  
21 I haven't seen such a motion, that there's not a similar issue  
22 with other cases. I know he's rendered an opinion in three  
23 cases, but with other case-specific experts on this basis.

24 MR. TARDIO: No, your Honor. The other case-specific  
25 experts followed the order.



1 THE COURT: Okay. All right. Who is going to speak  
2 on behalf of the plaintiffs?

3 MR. CHALOS: Mr. Gastel.

4 MR. GASTEL: Thank you, your Honor.

5 Obviously -- and we point this out in the papers --  
6 we disagree that he is offering a common opinion. If you look  
7 at the common opinions that we offered, they are generic  
8 opinions that this action could lead to injury, and Dr. --

9 THE COURT: It seems like most of the paragraphs have  
10 to do with general liability issues.

11 MR. GASTEL: And to a certain extent, there is some  
12 overlap there, but the ultimate conclusion in those reports is  
13 that that action caused specific injury to these three  
14 individuals.

15 THE COURT: Right. So, I had -- what I thought of  
16 case-specific experts -- and you can tell me why this was  
17 incorrect thinking. I had anticipated before reading Mr.  
18 Lee's report, that the report would have been saying this  
19 person had received this injection. It came from the tainted  
20 lot. This is what happened after he or she got the injection.  
21 These are the injuries that they suffered right after the  
22 injection and this is the person's prognosis. So, Mr. Lee's  
23 report seems very different than that.

24 MR. GASTEL: Well, Mr. Lee's report is still offering  
25 the specific -- case-specific opinion that the actions of the

1 defendant caused the injury -- or an injury to those three  
2 individuals, and I think -- and maybe this is sort of kind of  
3 the real sort of heart of the disagreement here -- is that,  
4 generally speaking, in MDL practice the purpose of a common or  
5 general or generic expert report are to give notice that the  
6 plaintiffs who ultimately litigate individual cases on behalf  
7 of individual plaintiffs can use the experts disclosed at the  
8 common phase, but not that they must use those experts.

9 And, again, the defendants haven't cited to any MDL  
10 court that has excluded a case-specific expert on the ground  
11 that he should have been disclosed at the common phase. That  
12 to me from my research into this issue is an utterly  
13 unprecedented position.

14 And ultimately, also, if you look at Rule 37, just  
15 assuming that the defendants are right and that it was  
16 untimely disclosed, again, you are permitted under Rule 37 to  
17 untimely disclose if there was a reason, a justifiable reason.  
18 Here, the plaintiffs reasonably thought that case-specific  
19 experts could opine on these issues.

20 THE COURT: But that didn't happen in any of the  
21 other cases.

22 MR. GASTEL: I'm sorry. In what other cases?

23 THE COURT: Well, I understand that Mr. Lee has  
24 rendered a report with respect to three plaintiffs. I  
25 understand from Mr. Tardio, there is not a similar issue with

1 respect to any other case-specific experts.

2 MR. GASTEL: That may be true, your Honor, because  
3 those plaintiffs -- the other plaintiffs who have had to  
4 disclose at this point have, I believe, disclosed the people  
5 who are disclosed at the common phase, which gets to another  
6 sort of underlying point about why this is unfair.

7 The PSC, who is in charge of doing the common and  
8 generic expert reports here, can't sort of dictate to other  
9 people down the road who is going to be their experts in their  
10 cases, but --

11 THE COURT: No, but they should follow the Court's  
12 orders.

13 MR. GASTEL: The plaintiffs --

14 THE COURT: Any party to the litigation.

15 MR. GASTEL: Sure. And, certainly, I don't think  
16 that anybody on the plaintiffs' side interpreted that they  
17 were going to be foreclosed from hiring the expert that they  
18 would have hired but for the PSC's disclosure of that expert.

19 The point being -- and this is particularly important  
20 in these kind of cases, your Honor, because, as you know, and  
21 as has been litigated before this Court under the Healthcare  
22 Liability Act, plaintiffs' lawyers have to start working with  
23 an expert relatively early in these cases, and the overwhelm  
24 -- and I believe that everybody has sort of submitted that 122  
25 certificate saying that they've worked with an expert and

1 they've opined on the merits of the underlying lawsuit.

2 And so, if they are to be believed, those plaintiffs  
3 who individually chose those experts at that early stage are  
4 now foreclosed from using those experts, and we don't think  
5 that that's a reasonable interpretation.

6 THE COURT: That's not necessarily so. Just because  
7 they chose them at the outset of the litigation doesn't mean  
8 they couldn't have complied with the Court deadlines for the  
9 different types of experts.

10 MR. GASTEL: Well, again, assuming that that was  
11 clear from the Court's previous orders, and I would say that  
12 it's reasonable to believe that that was not clear, given the  
13 way that the common points -- or common issues were described  
14 in that order.

15 THE COURT: It was a jointly-negotiated order. The  
16 PSC had input. The other defendants had input. There was  
17 back-and-forth on it about all the different meanings. It was  
18 a well-litigated issue, and no one sought any clarification  
19 after the order was entered.

20 MR. GASTEL: Yes. And this might be the first sort  
21 of practical implications of what that order meant.

22 THE COURT: I see. All right.

23 Anything further, Mr. Tardio?

24 MR. TARDIO: Yes, your Honor. This is an easy  
25 analysis in this instance, common versus case specific. If

1 Dr. Lee or Mr. Lee could say the same thing about every case,  
2 that's a common-issue expert and that applies here.

3 I don't understand why this is unfair to the  
4 plaintiffs. The plaintiffs, if my memory serves, are the ones  
5 -- that side actually offered the definitions of case specific  
6 and common.

7 So, on top of that, not to pick on Mr. Chalos, but  
8 he's disclosed in Wray and Zeigler, two cases that I know Mr.  
9 Chalos was involved in the negotiation or the litigation of  
10 that order in the first place. So, if it's unfair to anyone,  
11 allowing him to testify is unfair to the defendants.

12 THE COURT: All right. Thank you.

13 MR. CHALOS: Your Honor, may I be heard now?

14 THE COURT: Yes.

15 MR. CHALOS: My name has been mentioned, so I feel  
16 compelled to say something.

17 THE COURT: He said he wasn't trying to pick on you.

18 MR. CHALOS: Well, in that case -- no, I'm kidding.

19 So, yes. Matthew Lee is not a common expert. The  
20 common experts in this case are available for all plaintiffs  
21 to use. Dr. Lee specifically is not.

22 THE COURT: Right. So, whether or not he's  
23 designated as a common expert is different than whether his  
24 report contains common-expert type conclusions.

25 MR. CHALOS: Well, I understand, and I think I sort

1 of understood maybe for the first time their argument.

2 They're saying he's talking about common issues --

3 THE COURT: I actually thought your brief didn't  
4 understand their argument.

5 MR. CHALOS: Right. Yes. And he's talking about  
6 common issues and, you know, we've been sandbagged by these  
7 common issues -- this is their position -- and how dare they  
8 disclose an expert that we're going to have to now depose him.  
9 We've offered him for deposition, by the way. They didn't  
10 want to take his deposition.

11 They know all the common issues. They've heard from  
12 other experts. There are common experts that will address  
13 some of these issues.

14 THE COURT: Right, but that may be different than  
15 what Mr. Lee testifies about.

16 MR. CHALOS: Well, I sure hope it isn't. I hope it  
17 isn't.

18 But, in any event, he is not available for all  
19 plaintiffs. He's available for a very small number of  
20 plaintiffs. In our view, that makes him a case-specific  
21 expert. The fact that there are some common issues underlying  
22 his ultimate conclusion that this entity breached the standard  
23 of care with respect to Ms. Wray, with respect to Major  
24 Ziegler or with respect to Mr. Brock, does not convert him to  
25 a common expert available to all plaintiffs, and maybe that's

1 a distinction that we should have understood and applied in a  
2 way that's -- the Court understands the order to be, but we  
3 were making a very clear distinction that he is not a common  
4 expert available to any plaintiff who would like to use him.

5 So, to the extent that we didn't disclose him at the  
6 time that they believe we should have disclosed him, you know,  
7 I understand now their complaint about that, but that doesn't  
8 mean he doesn't get to testify on the issues that are in his  
9 report. We have plenty of time to have his deposition taken.  
10 If they think there are other experts they need to have  
11 address his opinions, you know, we'll work around that. We'll  
12 get them deposed. We'll get it ready for trial.

13 So, the extraordinary sanction of excluding what we  
14 believe to be the case-specific expert based on a disagreement  
15 about the process I think is not warranted here.

16 THE COURT: All right. Thank you.

17 MR. CHALOS: Thank you, Judge.

18 THE COURT: So, I'll move on to the Emory and  
19 Vanderbilt motions.

20 MR. GAETA: Your Honor, I'm Frank Gaeta, and I'm here  
21 for Emory and Vanderbilt.

22 THE COURT: I guess you can sit at that table...

23 (Discussion off the record.)

24 THE COURT: Do we actually have someone on the line?

25 (Discussion off the record at the Bench.)

1 THE COURT: You're welcome to sit down. You're  
2 welcome to stand. The reason for sitting down was to be able  
3 to speak closely to the microphones if there was someone on  
4 the phone.

5 MR. GAETA: Is there someone on the phone?

6 THE COURT: No. So, whatever you feel more  
7 comfortable. I think everyone else is used to sitting down  
8 while they present their arguments. So, you're welcome to do  
9 either one.

10 MR. GAETA: Okay. Thank you.

11 THE COURT: And, again, I have read the papers. So,  
12 if there's something you would like to add or point out in  
13 particular, I'm happy to hear you.

14 MR. GAETA: I'm happy to field any questions you  
15 have, your Honor.

16 You know, I just say that our argument is that the  
17 information sought is irrelevant. You don't have to reach a  
18 proportionality. If you're inclined to do so, then we believe  
19 that the miniscule, if any, value of the evidence to the cases  
20 is outweighed by the burden.

21 One development since we filed the motion is that we  
22 understand many of the non-parties to whom subpoenas were  
23 issued have, in fact, been deposed, which, I submit, is  
24 another reason why Emory and Vanderbilt ought not be required  
25 to testify. Their testimony is even less valuable than it



1 otherwise would be. It's unduly cumulative of the testimony  
2 of numerous other non-parties, which, we submit, is not  
3 relevant in the first instance.

4 THE COURT: All right. Thank you.

5 MR. WOLK: Your Honor, Christopher Wolk for the  
6 Premier defendants, and I'll address the motion. I'll address  
7 it briefly because I do know your Honor read the submissions.

8 But with regard to the relevancy argument -- and let  
9 me say this: We've had argument on this issue, I think, very  
10 similar to this -- similar argument with regard to these  
11 depositions by written question during the December hearing  
12 when the PSC raised the motion to quash these subpoenas and,  
13 in fact, the relevancy argument was brought up at that time.  
14 After reviewing the transcript, there was argument by the PSC  
15 that this information is not relevant, and your Honor ordered  
16 in December that the deposition by written question can go  
17 forward.

18 THE COURT: Right, but in response to all those  
19 arguments, it was the, I would say, narrowly crafted -- but  
20 perhaps that's for you all to decide, but that it was limited  
21 and this seems to go beyond the limitation.

22 MR. WOLK: The deposition by written questions that  
23 were submitted to Vanderbilt and to Emory are the same  
24 deposition by written questions that were at issue during the  
25 oral argument in December. They were the same 21 questions

1 that were submitted by --

2 THE COURT: I understand, but they say they didn't  
3 purchase any MPA.

4 MR. WOLK: With regard to Emory, they purchased  
5 injectable drugs.

6 And the relevancy argument, where it fails, is that  
7 this information can be used on two fronts. It's relevant, at  
8 the very least, to help the defendants prove causation. The  
9 allegations in this case are had the defendants performed  
10 their due diligence, they would have discovered certain  
11 information about NECC that would deter them from ordering  
12 from NECC.

13 This information, if answered by Emory and by  
14 Vanderbilt, if they answer the questions and say, In fact, we  
15 did an investigation into NECC and here is what we found, and  
16 what we found was that they were a reputable compounding  
17 pharmacy and that they used sterile technique and that we felt  
18 it appropriate to order from them, and that helps the  
19 defendants to prove that had we done the due diligence that  
20 they did -- that the plaintiffs say that we should have, that  
21 we would have found, if not the same information, very similar  
22 information.

23 We most recently took the deposition of one of the  
24 pharmacists in New Jersey for the Inspira network who, in  
25 fact, when asked, Did you do any due diligence before ordering

1 from NECC, he answered yes and gave us a litany of things that  
2 he did before ordering from them. All of that information is  
3 relevant to prove that had we done what the plaintiffs say we  
4 should, this is what we would have found. So, it goes to  
5 causation, at the very least. So, therefore, under that, it's  
6 relevant and that's where the Emory Clinic and the Vanderbilt  
7 Clinic's arguments fail on relevancy, but it also goes to  
8 standard of care as well.

9 The clinics argue that we can't substitute this  
10 information for expert testimony. We don't wish to substitute  
11 it for our experts' testimony. We will have experts that  
12 testify that we complied with the standard of care, but what  
13 we can use this information for is to buttress the standard of  
14 care, and that's done commonly.

15 We can't get this information from anyone else. We  
16 can't go and ask New England Compounding. We can't take their  
17 depositions until, as the Court has ordered, after the first  
18 criminal trial. So, we can't go to them and say, Did Emory  
19 and Vanderbilt contact you? Did they have conversations with  
20 you? Did they inspect? And that's the scope --

21 THE COURT: So, is Mr. Gaeta correct that you already  
22 have testimony from other non-parties who actually  
23 purchased -- and I think you've given an example of one who  
24 purchased MPA.

25 MR. WOLK: We do. In fact, we have -- between the

1 Premier defendants and the Box Hill defendants, I believe  
2 eleven deposition by written questions have been taken. All  
3 of those depositions by written questions, by the way, I  
4 believe have taken less than two hours to answer, some even  
5 less than an hour.

6 So, with regard to the burden outweighing the  
7 information that we can get, there really is -- the burden is  
8 very little. They have these deposition questions in advance.  
9 They can prepare for them. Most of the time has been spent  
10 reading the questions to the deponent. The answers have been  
11 relatively short.

12 Vanderbilt and Emory are two very large institutions  
13 that give an example in this case of not only what the  
14 standard of care is or was, but also, again, to the causation  
15 aspect, which is why they were chosen in the first place.

16 So, the cumulative aspect fails here because we have  
17 a cross-section of clinics, for example, like Premier was,  
18 locally in New Jersey, but we also have -- are seeking  
19 examples from larger institutions and what they do.

20 So, that's why the information -- it is relevant  
21 here, and the burden -- your Honor has already addressed the  
22 burden issue. This is a little bit different, I understand  
23 that. The argument for the burden is a little bit different,  
24 but it's the same questions. In fact, the questions ask the  
25 deponent about their due diligence before ordering from NECC.

1 Those were the questions from the beginning.

2 They do not address specifically MPA, because in this  
3 case what we're being faced with are allegations that we  
4 should have known about warnings from the FDA, the  
5 Massachusetts Board of Pharmacy, the congressional reports,  
6 all related to the dangers of compounding pharmacies, not the  
7 dangers of compounded MPA specifically.

8 There's been expert testimony in this case from the  
9 plaintiffs by one of their experts, Dr. Winiker, who stated  
10 very matter of factly, had you done any research, you would  
11 have determined it was illegal to order from compounding  
12 pharmacies. It was illegal to order from New England  
13 Compounding.

14 We may be faced with the very same criticisms in our  
15 case and we want to be armed with this information to combat  
16 those allegations, and I think that this is, again, a very  
17 economic way to do it. It's been taking an hour. It's  
18 deposition by written question. It's 21 questions. Our  
19 portion of the deposition takes 15 minutes to answer.

20 The plaintiffs have submitted cross-examination  
21 questions which expand the deposition to almost 100, sometimes  
22 200 questions. Those are not questions that we submitted,  
23 your Honor.

24 THE COURT: All right. Thank you. Anything further?

25 MR. GAETA: Yes, your Honor, just a couple of points.

1 I do want to emphasize that the Premier defendants  
2 are just changing their whole theory of relevancy right now in  
3 making this argument to you. They were crystal clear in their  
4 opposition to the PSC's motion for protective order in  
5 representing to the Court that Vanderbilt and Emory bought  
6 MPA, and I think they said explicitly that subpoenas were  
7 served on, quote, "nonparty entities who had purchased MPA  
8 from NECC prior to the outbreak." They said they were  
9 seeking, quote, "information about the due diligence conducted  
10 by these entities which form the informational basis for their  
11 decision to purchase MPA from NECC." They said, quote, "Their  
12 goal is to gather targeted information as to the due diligence  
13 conducted by other NECC customers who purchased MPA." Emory  
14 and Vanderbilt did not purchase MPA.

15 Your Honor, one other point that I didn't make in the  
16 brief is that the Premier defendants and the Box Hill  
17 defendants can point to the 3,000 or so nonparty entities who  
18 purchased medications from NECC.

19 It seems to me that the due diligence performed or  
20 lack thereof really is irrelevant to the ultimate question,  
21 which is whether the purchasing itself was negligent. The  
22 only thing that really matters with respect to that question  
23 is whether these nonparties bought, and the defendants can  
24 point to the fact that they bought or that they did a lot of  
25 due diligence before buying, a little bit of due diligence

1 before buying and were satisfied that the medications they  
2 were purchasing were safe. That's really the only evidence  
3 that matters in this context, and they have all that already.

4 THE COURT: All right. Thank you.

5 MR. WOLK: Your Honor --

6 THE COURT: I will take it under advisement.

7 You wanted to add something?

8 MR. WOLK: Just very, very, very briefly.

9 Mr. Gaeta and his clients are not parties to this  
10 case. This is discovery and things are changing. Things are  
11 evolving, as we see expert testimony and different theories.  
12 So -- and I want to bring up the point that Emory University  
13 -- or Emory Clinic did order an injectable sterile medication.  
14 MPA was an injectable sterile medication, but I submit, your  
15 Honor, that distinction doesn't even need to be made.

16 The allegations that we potentially face are when you  
17 order from a compounding pharmacy like New England  
18 Compounding, period, that's it, not what you ordered, just  
19 that when you order, you have to perform due diligence. This  
20 case is about due diligence.

21 I don't expect Mr. Gaeta to be familiar with all the  
22 theories in this case because he's not been through the  
23 litigation like the rest of us have, but that is, in fact, a  
24 theory that we will face in this case, and this information is  
25 highly relevant to that. It takes 21 questions to get the

1 information.

2 THE COURT: All right. Thank you. I will take it  
3 under advisement. You all are welcome to stay. It's a very  
4 interesting case and well argued on both sides, but I will  
5 also understand if you would like to leave as well.

6 MR. GAETA: Thank you, your Honor. I'm sure our  
7 client would rather not pay for us to stay, but I appreciate  
8 the offer.

9 (Attorneys Gaeta and Donohue are excused from the courtroom.)

10 THE COURT: So, moving on to the motion to quash the  
11 subpoenas with respect to various entities that employed Dr.  
12 Kessler.

13 MR. CHALOS: Ms. Martin is going to address that  
14 issue, your Honor.

15 MS. MARTIN: Thank you, your Honor.

16 None of these three subpoenas seek information  
17 relevant to Dr. Kessler's opinions here. Dr. Kessler's role  
18 here is to offer expert opinion on the regulatory authority of  
19 the FDA regarding compounding pharmacies. There's no question  
20 that he's qualified. He was appointed by the president, ran  
21 the FDA for seven years under two presidents. His opinions  
22 based on that experience are reliable.

23 The defendants here can't attack the substance of his  
24 opinions, so they're casting about now looking for something  
25 else to smear him with and, you know, they asked him already



1 about all of these topics at his deposition. Those questions  
2 were out of bounds then, but they asked them and chose to  
3 waste their deposition hours asking about irrelevant topics.  
4 He answered those questions then during the deposition.  
5 They're not entitled to just keep trying to get irrelevant  
6 information, try to dig something up on him to smear him with  
7 just because they can't attack the substance of his opinion,  
8 and it's not right and it's not what the subpoena power of  
9 this Court is for.

10 THE COURT: So, I don't believe -- and maybe I've  
11 forgotten. I'm not sure I've read it this week, but I believe  
12 the Tennessee folks raised your standing, the PSC's standing  
13 to seek to quash the subpoenas as opposed to, I assume, Dr.  
14 Kessler, and I don't think you addressed that in the brief.

15 MR. CHALOS: Right, your Honor. We are asserting Dr.  
16 Kessler's rights here, but, also, when these subpoenas were  
17 first served, we had communication with the recipients of the  
18 subpoenas and they -- the assistant general counsel, I  
19 believe, for Yale and somebody from the counsel's office at  
20 UCSF told us they did not intend to comply with the subpoenas.  
21 They believe them to be facially invalid for some  
22 deficiencies, including they didn't serve notice properly on  
23 the recipients.

24 So, we -- you know, they asked us whether we intended  
25 at that time to move to quash and to assert, essentially, the

1 rights to all the interested parties, and that's what we are  
2 purporting to do here, but we did not tell them not to comply.  
3 They told us they were not intending to comply and were going  
4 to rely on us to assert those rights to the Court.

5 THE COURT: All right.

6 MR. CHALOS: And Dr. Kessler, to the extent he's our  
7 expert, we're asserting his rights as well and his position is  
8 the same as ours on these issues.

9 THE COURT: All right. Who is going to speak on  
10 behalf of the defendants?

11 MR. GIDEON: I will, your Honor.

12 THE COURT: Yes.

13 MR. GIDEON: We did, indeed, raise the issue of  
14 standing. The oral argument did not address it. A request to  
15 file a late supplement, a response, was not made. There has  
16 been no submission by Mr. Chalos to verify anything that he  
17 just said about any conversation with general counsel for Yale  
18 or that they are now representing Dr. Kessler.

19 The commentary by Ms. Martin about this being an  
20 effort to smear or waste people's time is completely,  
21 completely wrong.

22 Tennessee has a competency statute for experts, which  
23 I think you've become quite familiar with over the last two  
24 years. STCA 29-26-115(b) says that you can't offer opinions  
25 about a healthcare provider unless you are licensed in

1 Tennessee or a contiguous bordering state and you were  
2 practicing a specialty that would make your testimony relevant  
3 in the case.

4           There are three topics that I asked Dr. Kessler about  
5 during his deposition. The reason I asked him is, as you well  
6 know, in most modern healthcare, in order to have staff  
7 privileges at any hospital, whether it's the smallest  
8 community hospital or the most prestigious tertiary facility,  
9 like Mass General, you have to have staff privileges; and,  
10 secondly, under the Joint Commission standards, you have to  
11 have in nearly every setting board certification.

12           So, I asked him about three areas: One is I asked  
13 him, "Do you have staff privileges?" And you'll see at Page  
14 58, Lines 11 down through 22, and then 59, 2 through 3.  
15 Typical of his responses -- I asked him if he had staff  
16 privileges, and he said no. He gave them up the last several  
17 years. "How long ago?" He sounded like Steve Martin. He  
18 said he had forgotten.

19           I asked him when he had not reapplied for staff  
20 privileges. When he was acting as a hospitalist, and he said  
21 he didn't know about that, and he said the last time he had  
22 any active hospitalist duties was some unspecified time in the  
23 past.

24           So, one of the subpoenas went to UCSF just asking  
25 this question: "When is the last time David Kessler had staff

1 privileges and a physician/patient relationship with anyone?"

2 I asked him, "When is the last time you admitted a  
3 patient to a hospital?" He didn't know, said he had no idea,  
4 but then he took a guess and he said it was probably between  
5 2007 and 2008.

6 The PSC in their filing at Document 2816 says it was  
7 in 2003. So, they know better than the person they represent  
8 in terms of when he last had staff privileges.

9 Those two -- two of the three then addressed just  
10 those simple subjects, and that is when did he last have staff  
11 privileges, and the other one went to the American Board of  
12 Pediatrics, which he said was the only entity that had ever  
13 given him board certification, and he couldn't recall when  
14 that expired.

15 The last point is this: I asked him, "Did you have a  
16 job lined up when you left the FDA February 28th, 1997?" He  
17 said no, but then, miraculously, said he was at home having  
18 come home from the dry cleaner and he got a call offering him  
19 the status as dean of the Yale School of Law. The way he said  
20 it and the timing just didn't make sense. So, we've issued  
21 one subpoena to Yale asking them simply to tell us when was  
22 the offer made to David Kessler.

23 They say it's designed to smear. It's only designed  
24 to inform, but it's also designed to inform us as to whether  
25 or not he will be qualified to offer opinion testimony under

1 the substantive competency standard.

2           There are two additional examples. We have waived  
3 oral argument on the issue of whether his deposition is  
4 completed or not, but in these pages you will find great  
5 examples of why we submit he is so evasive and we should get  
6 this information from a third party.

7           I asked him if he ever had a tort class, and he gave  
8 me the names of the professors. I asked him if he was  
9 licensed as a lawyer, and he tells me he's never taken a bar  
10 exam. His responses on these three other areas are just like  
11 that, intentionally evasive. We want to know the answers.  
12 That's why we've asked.

13           THE COURT: So, if I understand what you've said  
14 correctly, the subpoena to Yale is for impeachment purposes?

15           MR. GIDEON: Yes.

16           THE COURT: But even for impeachment purposes, it's  
17 not necessarily enough just to say impeachment purposes,  
18 because we're already tangentially associated, right?

19           MR. GIDEON: Correct.

20           THE COURT: I understand you get some discovery, but  
21 given that he answered the question at the deposition, you  
22 didn't like the answer, you find it miraculous, although  
23 someone who has held a very lofty position in the government,  
24 it may not be surprising that someone calls them as soon as  
25 they step down to offer them a job.

1 MR. GIDEON: It may be that he did get the call on  
2 Saturday, but it just doesn't seem reasonable to me that Yale  
3 School of Medicine would make a call on a Saturday after he  
4 has just stepped down and offering the position. It may be  
5 true, but then, again, I just want to know from Yale if, in  
6 fact, it is true.

7 THE COURT: But I had understood -- I had thought you  
8 wanted -- so, this was helpful -- the material about his board  
9 certification and the San Francisco hospital and medical  
10 school was, again, on impeachment issues, that perhaps he had  
11 practiced without the board certification, but it sounds to me  
12 like you're actually looking for it for a different issue.

13 MR. GIDEON: Well, it is for impeachment, too. Just  
14 as an example, the response by the PSC saying he last had  
15 clinical responsibilities in 2003, I don't know where they get  
16 that, but it's at odds with what he testified to. It has a  
17 dual purpose, impeachment as well as determining whether he is  
18 competent to offer opinion testimony under Tennessee's  
19 substantive competency standard.

20 Irrespective of being licensed in Tennessee or a  
21 contiguous bordering state, you have to have practiced a  
22 specialty that makes your testimony relevant, and if all he  
23 was doing was researching since 2003, he's not competent to  
24 offer any opinions in the case.

25 THE COURT: So, you're saying his work as

1 commissioner of the FDA grants him no special expertise?

2 MR. GIDEON: Yes, I am saying that. We will argue  
3 that later, but what I'm trying to demonstrate is, this isn't  
4 an effort to smear anybody. I just want to know the answers  
5 to these questions.

6 THE COURT: But at least you believe there's a  
7 potential to disqualify him as an expert under the Tennessee  
8 statute?

9 MR. GIDEON: Yes, your Honor, I do, and it's  
10 Subsection B, §TCA 29-26-115(b), which has a statutory  
11 competency standard, and I'll be happy to repeat it if you  
12 would like, but it's two elements, licensed in Tennessee or a  
13 contiguous bordering state and practicing that specialty  
14 during the year preceding the event. So, in this case it  
15 would be -- have to be practicing that specialty 2010 --

16 THE COURT: So, don't you already have that  
17 information? It sounds like he has stopped -- maybe I got the  
18 dates --

19 MR. GIDEON: I don't know. I don't know. He said he  
20 didn't know when he last had a physician/patient relationship.

21 THE COURT: Right, but I thought you said that under  
22 -- when you had gone through the analysis, that he would need  
23 to be board certified. At least by his own testimony, the  
24 last date was 2008.

25 MR. GIDEON: No. No. No. No. He said he had no

1 idea when he was last board certified, didn't have a clue at  
2 all, no idea, didn't even take a guess. He said that he  
3 thought he last had staff privileges at UCSF 2007 or 2008, but  
4 he prefaced it very carefully by saying, "I don't know." So,  
5 I don't know either, and all I want UCSF to tell us is when  
6 was that last date of staff privileges. It is just a fact.

7 MR. CHALOS: Your Honor, may I be heard?

8 THE COURT: Yes. Are you finished? And then I'll --

9 MR. GIDEON: I want to make sure I've answered all of  
10 your questions, and I'll yield if I have.

11 JUDGE ZOBEL: Yes, you have.

12 MR. GIDEON: Okay.

13 MR. CHALOS: So, Mr. Gideon -- I'm sure this is  
14 unintentional, but he's leaving out part of that statute that  
15 he cited to you. That statute applies to experts giving  
16 standard of care opinions. Dr. Kessler is not doing that.  
17 Dr. Kessler is giving opinions on -- and it's right in the  
18 statute, your Honor, you'll see it. He is giving opinions on  
19 FDA regulatory issues primarily, and his work at FDA is  
20 certainly relevant. His work as a pediatrician, which is what  
21 he's focused on -- and you can hear in his voice, he doesn't  
22 like Dr. Kessler and he's saying things like it's miraculous,  
23 and what have you, but --

24 MR. GIDEON: That's true, I don't.

25 THE COURT: Right, but as all good attorneys, we all



1 know that personal opinions don't really matter.

2 MR. CHALOS: They ought not to, but when they govern  
3 conduct and they dictate conduct, it ought not to be that way.  
4 They ought not to try to smear a person as a human being  
5 because they don't like them, admittedly.

6 But leaving that issue aside, he's not here  
7 testifying as a pediatrician --

8 THE COURT: It sounds like you all have spent too  
9 much time together, too.

10 MR. GIDEON: That's true, too. Absolutely the truth.

11 MR. CHALOS: He's not testifying as a pediatrician.  
12 He's not testifying as a dean of a medical school or a law  
13 school. He's testifying as an FDA regulatory expert. If they  
14 want to send subpoenas to the FDA, that's one thing. Sending  
15 subpoenas to Yale, sending subpoenas to UCSF where he was a  
16 practicing physician and administrator has nothing to do with  
17 his opinions. They don't seem to care about his opinions.  
18 That's the subject of another motion where they spend the  
19 entire time asking him about things other than his opinions,  
20 but his opinions are what they are. His subject matter is  
21 what it is. It is not a standard of care opinion. It's not  
22 as a pediatrician. It's not as a dean of Yale, and this is  
23 just a fishing expedition, way, way out of the main of what  
24 he's going to testify about at trial.

25 MR. GIDEON: I would, with your permission, like to

1 respond to that as well.

2 Mr. Chalos, apparently, has not paid attention to  
3 what his witness has been offered to say, and part of what  
4 this witness has been offered to say is that the folks at  
5 Saint Thomas Outpatient Neurosurgery Center should not have  
6 purchased because, and he has offered opinions critical of the  
7 decision making, the information they had, and their decision  
8 to purchase from NECC. That's all -- whether you call it  
9 standard of care or not, it is standard of care testimony.

10 The second thing is, §TCA 29-26-115(b) has no  
11 limitation to just standard of care. It applies to causation  
12 as well, which is also literally apparent in the statute. Dr.  
13 Kessler purports to offer the opinion that if they had done X,  
14 they would not have purchased and this wouldn't have occurred.  
15 He also offers the unqualified opinion that my folks are  
16 guilty of fraud.

17 The bottom line is, whether he is competent to  
18 testify is material at this stage. The burden associated with  
19 getting this information is minimal. It directly deals with  
20 both impeachment and it deals with qualifications, and I will  
21 repeat, to close, we respectfully submit that they do not have  
22 the right to assert the rights of others, whether it's Dr.  
23 Kessler or Yale or the American Board of Pediatrics, who have  
24 not made any appearance here and deputized them to speak for  
25 them today. Thank you.

1 THE COURT: Do I have -- in some other pleadings I  
2 have not read for today's hearing, do I have Dr. Kessler's  
3 report somewhere? Has it been filed somewhere else?

4 MR. CHALOS: I believe you do, but we can certainly  
5 submit it today.

6 MR. GIDEON: Judge Boal, I believe it is an exhibit  
7 to the deposition that was filed with our motion to compel  
8 completion, but would you like me to check and make sure --

9 THE COURT: Well, I have that right here.

10 MR. GIDEON: Okay.

11 THE COURT: Let me just check.

12 (Pause.)

13 MR. GIDEON: The exhibit should be separately tabbed.

14 THE COURT: They are.

15 MR. GIDEON: And there should be an index, I think,  
16 Page 4 of the transcript or thereabouts.

17 THE COURT: You know this too well.

18 MR. GIDEON: Yeah.

19 (Pause.)

20 THE COURT: Right. It looks like it was -- is this  
21 possible? Were there 1,250 exhibits at this deposition?

22 MR. GIDEON: Yes -- well, no. The numbers are  
23 sequential for the entire case. So, it's not --

24 THE COURT: Okay. I was going to say, that's a lot  
25 of exhibits.

1 MR. GIDEON: No, your Honor, that is not for this  
2 deposition. We have been sequentially numbering these for the  
3 entire life of the litigation.

4 THE COURT: Makes a lot of sense.

5 So, it looks like it's Exhibit 1,250. I'm just not  
6 -- or Exhibit F here. Okay. All right. Well, we'll see if  
7 we have it.

8 MR. GIDEON: If you do not, just a minute entry  
9 saying submitted and we'll do it.

10 THE COURT: Okay. That would be great.

11 MR. GIDEON: Good.

12 THE COURT: All right. Moving on to the motion to  
13 strike the Mixon supplemental.

14 MR. CHALOS: Mr. Gastel will address that.

15 MR. GASTEL: Your Honor, I was under the impression  
16 you did not want oral argument, but I am here to answer any  
17 question you might have on the motion. The plaintiffs are  
18 prepared to waive oral argument.

19 THE COURT: All right. Do the defendants wish to add  
20 anything?

21 MR. TARDIO: No. The only point I would add is that  
22 if the Court believes this to truly be a supplemental opinion  
23 that has somehow prejudiced the plaintiffs, I think the easy  
24 remedy is an hour deposition by phone. They don't need to see  
25 Mixon again in person to ask him about this one paragraph.

1 THE COURT: Well, what if I was to conclude that it  
2 wasn't supplemental, but that it was a new opinion?

3 MR. TARDIO: I, respectfully, disagree that it is a  
4 new opinion. I think it folds entirely within what he said in  
5 his deposition in the areas he was disclosed to testify on,  
6 and even if it is a new opinion, I think the proper remedy,  
7 the fair remedy, is still a one-hour deposition by phone. I  
8 can't imagine it would take longer than that.

9 MR. GASTEL: May I just point out, your Honor --

10 THE COURT: Yes.

11 MR. GASTEL: -- that it's striking, the difference  
12 between the treatment that they're proposing for Nixon and the  
13 treatment that they're proposing for Dr. Lee.

14 THE COURT: Actually, you both are switching  
15 positions on that.

16 MR. TARDIO: Well, I entirely disagree.

17 THE COURT: Okay.

18 MR. TARDIO: I think that those are -- even though  
19 the same concepts and rules are invoked in both arguments, Dr.  
20 Lee -- I've never seen him. I've never asked him about  
21 anything, and he's an entirely new expert.

22 Dr. Nixon they saw for six or seven hours. They  
23 asked him about whatever they wanted to ask him about. They  
24 have seen him. They've tested him. They've evaluated him.  
25 They've pressed him on all of these issues. They just have

1 not asked in their opinion questions about this supplemental  
2 opinion. So, I don't think that these are -- I mean, they're  
3 somewhat similar, the analysis, but I think they're entirely  
4 different situations.

5 THE COURT: So --

6 MR. GASTEL: Just to make clear, your Honor, the  
7 supplement was provided after Mr. Mixon's deposition.

8 THE COURT: Right. So, the issue had been contained  
9 in the master complaint, right, about the allegation that it  
10 was, I guess, bad practice to order nonpatient-specific  
11 prescriptions. So, do you have other expert -- why wasn't  
12 this addressed in the original report?

13 MR. TARDIO: Well, maybe it should have been. That's  
14 not his primary -- the primary reason we retained him, and  
15 maybe it should have been, and I don't disagree that you can  
16 make a good argument that it should have been in the original  
17 report. It wasn't. Can't change that.

18 He said in his deposition it was routine to provide  
19 office use compounding medications for doctors who treated  
20 pain prior to 2012. The issue was covered. I think if we  
21 look at the intent of the rules, which is to make sure the  
22 other side is on notice of what he's going to say at trial, I  
23 think the plaintiffs are on notice, and we could argue all day  
24 about whether it should or shouldn't have been in the original  
25 report. It wasn't, and that's why we supplemented it.

1           This comes up all the time. You're in that difficult  
2 position, do I supplement the report and face a motion like  
3 this? Do I not supplement the report? And then at trial he  
4 says something that's not within the four corners of the  
5 report and it comes up at trial.

6           THE COURT: Well, it's better to know.

7           MR. TARDIO: Well, I think the fair thing to do is to  
8 supplement and deal with it after.

9           THE COURT: So, did you not supplement -- I mean, it  
10 doesn't really matter why, but, in my own mind, I was thinking  
11 perhaps you hadn't supplemented because you have other experts  
12 that are going to talk to this issue.

13          MR. TARDIO: Other experts will talk to this issue,  
14 yes.

15          THE COURT: All right.

16          MR. GIDEON: Your Honor?

17          THE COURT: Yes.

18          MR. GIDEON: There's one last thing that I think the  
19 Court should take into consideration, to be candid with you.  
20 Mr. Mixon's significance in the case was enhanced after I took  
21 the deposition of Richard Rauck, R-a-u-c-k, who is a pain-  
22 control physician and founder of the Carolina's pain clinic.  
23 I didn't know when I went to depose him, but found out when I  
24 was deposing him in April, that he had fired a prior  
25 compounder as a result of patient injury and then had selected

1 Mr. Nixon.

2 So, Mr. Nixon was the chosen compounder selected by  
3 one of the flagship witnesses for the plaintiffs, which raised  
4 additional attention on our part to Mr. Nixon's role in the  
5 litigation. So, that is a candid concession about something  
6 Mr. Wolk mentioned earlier, and that is the dynamic changes  
7 that go along during the course of the case.

8 THE COURT: Thank you.

9 MR. CHALOS: Your Honor, if I may.

10 And I hope I'm not speaking out of school here with  
11 my colleagues, but we would be willing to exchange a little  
12 bit of grace here on this and withdraw our opposition to their  
13 supplement of Mr. Nixon in exchange for their withdrawing  
14 their challenge to Dr. Lee.

15 MR. GIDEON: No.

16 MR. CHALOS: Recognizing that things change in the --

17 THE COURT: Well, since you -- I think we're about  
18 done here. There's a little time before the Judge Zobel  
19 session. If you all can reach an agreement, that's fine. I  
20 would suggest, given the pace that Judge Zobel has it on, that  
21 if you do agree, I would suggest that you pick dates for the  
22 completion of any additional discovery in the next two weeks  
23 or so, but if you -- you don't need to tell me at the 2  
24 o'clock, but if you want to file something tomorrow by close  
25 of business saying whether you've been able to resolve the two



1 issues, that's fine.

2 MR. CHALOS: Thank you, your Honor.

3 THE COURT: Anything else?

4 MR. CHALOS: Not from us, your Honor.

5 THE COURT: I'll see you at 2 o'clock.

6 COURTROOM DEPUTY CLERK YORK: All rise. The Court is  
7 in recess.

8 (Adjourned, 12:35 p.m.)  
9  
10  
11

12 C E R T I F I C A T E

13 I, Catherine A. Handel, Official Court Reporter of the  
14 United States District Court, do hereby certify that the  
15 foregoing transcript, from Page 1 to Page 41, constitutes to the  
16 best of my skill and ability a true and accurate transcription of  
17 my stenotype notes taken in the matter of No. 13-md-2419-RWZ, In  
18 Re: New England Compounding Pharmacy, Inc., Products Liability  
19 Litigation.  
20

21 July 10, 2016  
22 Date

/s/Catherine A. Handel  
Catherine A. Handel RPR-CM, CRR  
23  
24  
25